

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

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CHRISTEL BILLHOFER, On Behalf of	:
Herself and All Others Similarly Situated,	:
	:
Plaintiff,	:
	:
	:
vs.	:
	:
FLAMEL TECHNOLOGIES, SA, STEPHEN	:
H. WILLARD, and RAFAEL JORDA,	:
	:
Defendants.	:
-----	X

Civ. No. 07 Civ. 9920 (CSH)
(ECF Case)

**MEMORANDUM OF LAW BY FLAMEL TECHNOLOGIES, SA
IN SUPPORT OF ITS MOTION TO DISMISS THE AMENDED COMPLAINT**

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Dated: May 12, 2008

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Defendant Flamel Technologies, SA ("Flamel") respectfully submits this memorandum of law in support of its motion, pursuant to Rules 9(b) and 12(b)(6) of the Federal Rules of Civil Procedure and the Private Securities Litigation Reform Act ("PSLRA"), 15 U.S.C. §78u-4(b), to dismiss, with prejudice, the claims asserted against it in the Amended Complaint, dated March 27, 2008 (the "Amended Complaint" or "AC").¹

PRELIMINARY STATEMENT

Plaintiff's purported securities fraud action should be dismissed with prejudice for two reasons -- it fails to properly plead (a) that plaintiff purchased her Flamel securities in reliance upon a material misstatement; and (b) facts raising a strong inference that Flamel (or the individual defendants) acted with scienter.

The Amended Complaint accuses Flamel of violating §§10(b) and 20(a) of the Securities Exchange Act of 1934 by promoting the commercial viability of COREG CR -- a drug for the treatment of congestive heart failure -- based on performance criteria it knew (or recklessly failed to know) were not achievable. Flamel, which develops "polymer-based delivery technologies," collaborated with the pharmaceutical company GlaxoSmithKline ("GSK") to create COREG CR, an "improved" version of "COREG IR" -- a drug that GSK had originally developed and marketed. The benefit of COREG CR was that, using Flamel's technology, it delivered its active ingredient through an "extended release" formula, allowing patients to take one dosage per day versus COREG IR's "immediate release" formula, which required two dosages per day.

¹ Stephen H. Willard and Rafael Jorda, who are officers of Flamel and reside in France, are named as defendants but have never been served with process.

Plaintiff contends that Flamel, in a series of six statements -- beginning with a March 23, 2007 press release announcing COREG CR's market launch and continuing through August 2, 2007 -- overstated COREG CR's future sales potential by claiming that COREG CR's reduced dosage requirement would result in improved patient compliance rates with their doctor's prescriptions. Plaintiff charges that Flamel knew (or recklessly failed to know) its sales predictions for COREG CR were false because, prior to March 23, 2007, it had "commenced" a clinical study comparing patient compliance rates between COREG IR and COREG CR -- known as the "CASPER Trial" -- which found that COREG CR was "not associated with better drug-taking compliance." Plaintiff alleges that, when an abstract of the CASPER Trial findings was published on August 23, 2007 in the *Journal of Cardiac Failure*, Flamel's stock dropped.

Plaintiff's allegations fail to properly allege the essential elements of a §10(b) claim. First, despite her criticisms of six Flamel statements, plaintiff purchased all her Flamel securities on April 24, 2007, following only the first of Flamel's statements at issue -- *i.e.*, the March 23, 2007 COREG CR product announcement. That disclosure did not mention patient compliance rates or future product sales. Rather it consisted entirely of historical statements whose accuracy is not challenged. Moreover, to extent that any of its statements -- *e.g.*, that the successful introduction of COREG CR "has generated considerable interest" in Flamel's technologies -- could be misconstrued as a prediction of future success, the statements are too vague and imprecise to be considered material, as a matter of law.

Second, the conclusory allegations of the Amended Complaint fail to raise a strong inference of scienter. Plaintiff does not identify any concrete motive to explain why Flamel would seek to deceive investors. Indeed, the fraudulent scheme plaintiff has concocted is economically nonsensical, because it assumes that Flamel publicly overstated COREG CR's

performance criteria beginning in March 2007 despite (a) knowing that, by August 2007, publication of the CASPER Trial abstract would show those claims to be false; (b) failing, in the interim, to obtain any benefit from the allegedly inflated performance claims; and (c) continuing, in the interim, to invest substantial resources in manufacturing COREG CR. Because such a scheme is inconsistent with Flamel's "informed economic self-interest" it cannot raise an inference of fraudulent intent.

Furthermore, plaintiff's assertion that, prior to March 23, 2007, Flamel knew the results of the CASPER Trial is wholly conclusory and lacks any factual support linking anyone at Flamel to knowledge of the results of the CASPER Trial **before** the August 23, 2007 publication of the Trial abstract. Indeed, the facts pled -- and the documents plaintiff relies upon -- raise a compelling argument that Flamel was unaware of the Trial results prior to the abstract's publication. In short, plaintiff's allegations of scienter are nothing but an improper attempt to plead fraud by hindsight. Accordingly, plaintiff's §10(b) claim and her derivative §20(a) claim should be dismissed with prejudice.

THE ALLEGATIONS OF THE AMENDED COMPLAINT

For the Court's convenience, the allegations of the Amended Complaint relevant to this motion are summarized below.

A. The Parties

Plaintiff Christel Billhofer is an individual who allegedly purchased 900 American Depositary Receipts² ("ADR") of Flamel common stock on April 24, 2007. (AC ¶ 3 &

² An ADR is a "means by which American investors hold and trade equity interests in foreign companies." *Gas Natural v. E.On AG*, 468 F. Supp. 2d 595, 596 n.1 (S.D.N.Y. 2006). In essence, the foreign corporation "must issue and deposit American Depositary Shares ("ADSs") with an American financial institution" which then issues ADRs "to the beneficial owners of the ADSs, who may sell the

Billhofer certification.³) Plaintiff seeks to represent a class of all persons who purchased Flamel ADRs during the period March 23, 2007 through August 22, 2007. (*Id.* ¶¶ 1, 7.)

Flamel is a publicly-held, French company whose ADRs are traded on the NASDAQ. (*Id.* ¶ 4.) Flamel's business consists of developing "polymer-based delivery technologies for medical applications." In particular, it "specializes in helping pharmaceutical companies develop extended release drugs." (*Id.* ¶ 13.) Defendants Stephen H. Willard and Rafael Jorda serve, respectively, as Flamel's Chief Executive Officer and Chief Operating Officer. (*Id.* ¶¶ 5-6.)

B. The Events At Issue

Plaintiff's action focuses upon the introduction and marketing of a drug named "COREG CR," which is designed, among other things, to treat "moderate to severe congestive heart failure." (*Id.* ¶ 14.) Prior to the introduction of COREG CR, the pharmaceutical company GSK had developed and marketed a similar drug named "COREG IR," which delivered its active ingredient through an "immediate release" mechanism. (*Id.* ¶ 15.) GSK, in collaboration with Flamel and its "polymer-based delivery technologies," developed a "controlled release" version of COREG IR which became COREG CR. (*Id.*)

The benefit of COREG CR was that it could be dispensed in once-a-day dosages, whereas COREG IR needed to be taken twice-a-day. (*Id.* ¶¶ 15-16.) According to the Amended Complaint, it was "widely known that a primary issue for users of cardiac medication is compliance" with their medication regimen. (*Id.* ¶ 16.)

ADSs on American securities exchanges." *Id.* See also *Pinker v. Roche Holdings Ltd.*, 292 F.3d 361, 367 (3d Cir. 2002)(describing ADR securities).

³ A copy of Ms. Billhofer's certification, which was filed with her initial pleading, is attached as Exhibit A to the Declaration of David Wertheimer, executed on May 12, 2008 ("Wertheimer Decl.").

Plaintiff contends that Flamel falsely promoted the future sales potential of COREG CR by claiming that its reduced dosage requirement would lead to improved patient compliance rates and increased demand by the medical community. Plaintiff asserts that Flamel first made its misleading claims in a March 23, 2007 press release announcing COREG CR's product launch. That disclosure, however, did not refer to patient compliance rates or COREG CR's sales potential. Rather, in relevant part, it said:

We are pleased that COREG CR™ will now be available to patients in the U.S. for the treatment of these three serious conditions. COREG CR™ is the first marketed product incorporating Flamel's MICROPUMP® technology. The success of the COREG CR™ program has generated considerable interest in our MICROPUMP® technology as well as in our MEDUSA® technology platform for the delivery of proteins and peptides. Interest in both technologies has never been higher.

(*Id.* ¶ 22.) Plaintiff claims that Flamel continued to publish allegedly inflated sale projections in five additional press releases, filings with the Securities and Exchange Commission and analyst conference calls on April 30, May 7, August 1 and August 2, 2007. (*Id.* ¶¶ 23-27.)

Plaintiff alleges that these several statements were revealed to be false by the publication on August 23, 2007 of an abstract in the *Journal of Cardiac Failure* describing the results of a clinical trial known as the "CASPER Trial." (*Id.* ¶¶ 19, 21, 28-29.) The CASPER Trial was designed to "measure the differential compliance, quality of life and satisfaction with medication in chronic heart failure patients taking COREG IR vs. COREG CR." (*Id.* ¶ 18.) According to plaintiff, the abstract disclosed that the CASPER Trial had concluded "that switching from COREG IR to COREG CR was not associated with better drug-taking compliance," which undermined "the primary selling point for COREG CR." (*Id.* ¶¶ 20, 28.)

Plaintiff alleges that, prior to issuing its first alleged misstatement on March 23, 2007, Flamel was aware of the results of the CASPER Trial. The only purported basis for that conclusion appears in the following three paragraphs of the Amended Complaint:

18. In order to prove the benefits of COREG CR, GSK and Flamel commenced a clinical trial to measure the differential compliance, quality of life and satisfaction with medication in chronic heart failure patients taking COREG IR vs. COREG CR (the "Casper Trial"). The primary outcome of the CASPER Trial was pill-taking compliance.

19. By no later than the start of the Class Period, the CASPER Trial was complete and the results were made known to GSK and Flamel. An abstract of the CASPER Trial was required to be submitted to the *Journal of Cardiac Failure* by no later than April 9, 2007. To meet this deadline, GSK and Flamel were required to complete the CASPER Trial, analyze the associated data, and draw conclusions therefrom -- all sufficiently in advance of the submission date.

20. The abstract of the CASPER Trial, which was submitted to the *Journal of Cardiac Failure*, concluded that switching from COREG IR to COREG CR 'was not associated with better drug taking compliance. ...' **Thus, the primary selling point for COREG CR was not supported by the CASPER Trial.**

(*Id.* ¶¶ 18-20.)

Based on the foregoing allegations, plaintiff purports to assert claims against all defendants for violations of §§10(b) and 20(a) of the Securities Exchange Act of 1934.

ARGUMENT

I. PLAINTIFF'S §10(B) CLAIM SHOULD BE DISMISSED

To allege a claim under §10(b), plaintiff must plead that Flamel "(1) made misstatements or omissions of material fact, (2) with scienter, (3) in connection with the purchase or sale of securities, (4) upon which the plaintiff relied, and (5) that the plaintiff's reliance was the proximate cause of its injury." *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493

F.3d 87, 105 (2d Cir. 2007).⁴ Moreover, plaintiff's allegations must satisfy the heightened pleading requirements of Rule 9(b) of the Federal Rules of Civil Procedure and the PSLRA. *Id.* at 99. The Amended Complaint fails to satisfy these requirements.

A. Plaintiff Fails To Allege A Material Misstatement

Despite challenging six public statements by Flamel, plaintiff acknowledges that she purchased all her Flamel securities on April 24, 2007 after Flamel had issued, on March 23, 2007, only the first of its supposed six misstatements. Accordingly, if Flamel's March 23, 2007 statement is not actionable, plaintiff may not assert a §10(b) claim for herself or on behalf of anyone else. *Denny v. Barber*, 576 F.2d 465, 468-69 (2d Cir. 1978)(if plaintiff "cannot share in any recovery because no fraudulent statements were issued before his purchase, he would not be a proper representative of persons who bought securities after fraudulent statements were issued if indeed this occurred").⁵ As shown below, Flamel's March 23, 2007 press release is not actionable as a matter of law.

A statement is materially misleading only if it "would have misled a reasonable investor." *Rombach v. Chang*, 355 F.3d 164, 172 n.7 (2d Cir. 2004). It follows that the omission of information is actionable only where it is "sufficiently connected to Defendants' existing disclosures to make those public statements misleading." *In re FBR Inc. Sec. Litig.*, 05

⁴ *Accord Stoneridge Investment Partners, LLC v. Scientific-Atlanta, Inc.*, 128 S.Ct. 761, 768 (2008).

⁵ *Accord Gross v. Summa Four, Inc.*, 93 F.3d 987, 993 (1st Cir. 1996)(plaintiff who purchased securities before misstatements "has no standing to complain about the statements" and "cannot maintain an action on behalf of class members to redress an injury for which he has no standing in his own right"); *Roots Partnership v. Lands' End, Inc.*, 965 F.2d 1411, 1420 (7th Cir. 1992)("post-purchase statements cannot form the basis of Rule 10b-5 liability, because the statements could not have affected the price at which plaintiff actually purchased"); *In re Career Education Corp. Sec. Litig.*, 03 C 8884, 2006 WL 999988, at *2-3 (N.D. Ill. Mar. 28, 2006)(plaintiff cannot assert §10(b) action for himself or class based on statements post-dating his purchase); *Levine v. NL Indus.*, 720 F. Supp. 305, 308 (S.D.N.Y. 1989)(same).

Civ. 4617 (RJH), 2008 WL 857627, at *8 (S.D.N.Y. Mar. 31, 2008). The gist of plaintiff's claim is that Flamel's disclosures -- including its March 23, 2007 press release -- were misleading because they omitted that the CASPER Trial had found that COREG CR did not result in "better drug-taking compliance," which undermined the "primary selling point for COREG CR." (AC ¶¶ 20, 28.)

Plaintiff's contention that the statements in Flamel's March 23 press release triggered an obligation to disclose the omitted information, however, is belied by the plain text of the statement, which said:

We are pleased that COREG CR™ will now be available to patients in the U.S. for the treatment of these three serious conditions. COREG CR™ is the first marketed product incorporating Flamel's MICROPUMP® technology. The success of the COREG CR™ program has generated considerable interest in our MICROPUMP® technology Interest in both technologies has never been higher.

(AC ¶ 22.)

Nothing in the March 23 press release refers to or otherwise implicates patient's compliance rates for COREG CR. Nor is there any discussion of the future marketing potential of COREG CR. Rather, because these statements do no more than discuss the historical performance of COREG CR's introduction -- whose accuracy is not challenged -- they cannot, as a matter of law, be found misleading for omitting discussion of potential future sales performance. Indeed, it is well-established that defendants "'may not be held liable under the securities laws for accurate reports of past successes, even if present circumstances are less rosy.'" *In re Duane Reade Inc. Sec. Litig.*, 02 Civ. 6478 (NRB), 2003 WL 22801416, at *6 (S.D.N.Y. Nov. 25, 2003), *aff'd*, 107 Fed. Appx. 250 (2d Cir. 2004).⁶

⁶ *Accord In re Sierra Wireless, Inc. Sec. Litig.*, 482 F. Supp. 2d 365, 374 (S.D.N.Y. 2007)(accurate statement of historical earnings not misleading even if future results known to be less promising); *In re*

Moreover, even if statements in the March 23 press release could be misconstrued as projections of COREG CR's future marketing success, the statements are nothing more than "expressions of puffery and corporate optimism" which, as a matter of law, "do not give rise to securities violations." *Rombach*, 355 F.3d at 174. Indeed, it is well-established that "'loosely optimistic statements that are so vague, so lacking in specificity, or so clearly constituting the opinions of the speaker, that no reasonable investor could find them important'" are deemed immaterial as a matter of law. *In re eSpeed, Inc. Sec. Litig.*, 457 F. Supp. 2d 266, 280 (S.D.N.Y. 2006).⁷

In the case of the March 23 press release, to the extent that any of the statements might have been mistakenly viewed as projections -- *e.g.*, the "success of the COREG CR™ program has generated considerable interest in our MICROPUMP® technology" or that interest in Flamel's technology "has never been higher" -- the expressions are simply garden variety "rosy affirmation" of corporate optimism that courts have routinely found immaterial as a matter of law. *See id.* at 280, 286 (statement that defendant "'look[s] forward to growing this business as more and more users recognize PI's tremendous benefit' is non-actionable puffery").⁸ Accordingly, plaintiff's §10 (b) claim must fail.

QLT Inc. Sec. Litig., 312 F. Supp. 2d 526, 535 (S.D.N.Y. 2004)("A correct statement of fact is not a misrepresentation and cannot, therefore, support a cause of action for securities fraud."); *In re WorldCom, Inc. Sec. Litig.*, 303 F. Supp. 2d 385, 387 (S.D.N.Y. 2004)("accurate description of historical prices" cannot be materially misleading).

⁷ *Accord Lasker v. New York State Elec. & Gas Corp.*, 85 F.3d 55, 58 (2d Cir. 1996)("Statements that a company is committed to increasing earnings, convinced of its business strategy, and has set its most aggressive goals ever are not considered seriously by the marketplace and investors in assessing a potential investment").

⁸ *See also San Leandro Emergency Medical Group Profit Sharing Plan v. Philip Morris Cos., Inc.*, 75 F.3d 801, 811 (2d Cir. 1996)(defendant's "general announcements ... that it was 'optimistic' about its earnings and 'expected' Marlboro to perform well" were non-actionable puffery); *Kemp v. Universal American Financial Corp.*, 05 Civ. 9883(JFK), 2007 WL 86942, at *14 (S.D.N.Y. Jan. 10,

B. Plaintiff Fails To Allege Facts Raising A Strong Inference Of Scienter

The element of scienter "requires a showing of 'intent to deceive, manipulate, or defraud,' which includes consciously reckless misconduct. *ATSI*, 493 F.3d at 99 n.3.⁹ The PSLRA directs that such a showing may be accomplished only by alleging "with particularity facts giving rise to a strong inference" of scienter. 15 U.S.C. §78u-4(b)(2). That requirement may be satisfied by "alleging facts (1) showing that the defendants had both motive and opportunity to commit the fraud or (2) constituting strong circumstantial evidence of conscious misbehavior or recklessness." *ATSI*, 493 F.3d at 99.¹⁰ The facts alleged, however, must support an inference of scienter that is "more than merely plausible or reasonable -- it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 127 S.Ct. 2499, 2505 (2007). In this case, such facts are wholly absent from the Amended Complaint and thus plaintiff's §10(b) claim must fail.

2007)(dismissing as puffery company's statement that it is "very optimistic about our ability to keep growing the ... business" and "is well-positioned to offer the full range of needed products"); *Sierra Wireless, Inc.*, 482 F. Supp. 2d at 373 (dismissing as puffery defendant's statements that it "expected OEM to continue to be a strong segment" and "OEM would continue to be a healthy business for the foreseeable future"); *The City of Sterling Heights Police and Fire Retirement System v. Abbey Nat'l, PLC*, 423 F. Supp. 2d 348, 357-358 (S.D.N.Y. 2006)(dismissing as puffery statements that company "is in better shape than ever," that it "projected a 'strong track record of double digit profit growth,'" and that it "is in very good shape as it moves into the next stage of its development" and "well placed to take advantage of future opportunities"); *In re Bristol Myers Squibb Sec. Litig.*, 312 F. Supp. 2d 549, 557-559 (S.D.N.Y. 2004)(finding immaterial company's statement that its product was "a tremendous strategic opportunity;" has "real blockbuster potential, has the potential to be one of the most exciting, if not the most exciting, oncology compound introduced over the next several years;" and has "potential to drive the growth of our oncology franchise in the near and medium term").

⁹ *Accord Novak v. Kasaks*, 216 F.3d 300, 312 (2d Cir. 2000)("scienter requirement can be satisfied by pleading either 'conscious recklessness' -- i.e., a state of mind 'approximating actual intent, and not merely a heightened form of negligence' -- or 'actual intent.'"); *Fadem v. Ford Motor Co.*, 352 F. Supp. 2d 501, 517 (S.D.N.Y. 2005)(Haight, J.)(same).

¹⁰ *Accord In re Elan Corp. Sec. Litig.*, 05 Civ. 2860 (RJH), 2008 WL 839744, at *20 (S.D.N.Y. Mar. 27, 2008); *In re Pfizer, Inc. Sec. Litig.*, 06 Civ. 14199 (LAK), 2008 WL 540120, at *7 (S.D.N.Y. Feb. 28, 2008); *Goplen v. 51Job, Inc.*, 453 F. Supp. 2d 759, 771 (S.D.N.Y. 2006)(Haight, J.).

1. Plaintiff does not allege that Flamel had a motive to commit fraud

A "motive" to commit fraud is pled by factual allegations demonstrating that "defendants benefitted in some concrete and personal way from the purported fraud." *Novak*, 216 F.3d at 307-08.¹¹ No such allegations appear in the Amended Complaint.

For example, plaintiff does not allege that Flamel sought to inflate its stock price in order to complete a specific corporation acquisition nor does plaintiff contend that the individual defendants sold any of their stock -- let alone engaged in "suspicious" stock sales. Compare *In re Geopharma, Inc. Sec. Litig.*, 399 F. Supp. 2d 432, 442 (S.D.N.Y. 2005) (identifying factual scenarios which may plead motive). Indeed, plaintiff fails to offer a single reason to explain why Flamel would issue its supposedly misleading statements.¹²

Worse still, the fraudulent scheme outlined in the Amended Complaint "defies economic reason." According to plaintiff, Flamel issued misleading statements about COREG CR during the period March 23 through August 2, 2007 despite purportedly knowing that (a) an abstract of the CASPER Trial would be submitted to the *Journal of Cardiac Failure* "by no later than April 9, 2007" for publication in August 2007 and (b) the abstract showed that COREG CR "was not associated with better drug taking compliance" and thus supposedly undermined all the public statements Flamel made about COREG CR during the purported class period. (AC ¶¶ 18-21.) In short, plaintiff contends that Flamel, knowing with certainty that the falsity of its

¹¹ *Accord Goplen*, 453 F. Supp. 2d at 772; *Fadem*, 352 F. Supp. 2d at 523-24.

¹² Plaintiff suggests, in passing, that the success of COREG CR was "critical" because of the need to "transition users to COREG CR from COREG IR before generic competition entered the market." (AC ¶ 15.) Such an incentive, however, would only apply to GSK, the developer and marketer of COREG IR, and not Flamel. Moreover, the general desire to successfully market a product falls far short of alleging the "concrete benefits" which Rule 9(b) and the PSLRA demand to plead motive. See *Rombach*, 355 F.3d at 177 ("Action taken to 'maintain the appearance of corporate profitability, or of the success of an investment ... does not entail concrete benefits' sufficient to demonstrate motive.").

supposedly misleading statements would be revealed within five months of their first issuance, nevertheless embarked on its fraudulent scheme.

Such an implausible theory must be rejected. Courts in the Second Circuit have repeatedly held that defendants are assumed to act in their "informed economic self-interest" and therefore have concluded that a theory which "'defies economic reason ... does not yield a reasonable inference of fraudulent intent.'" *Shields v. Citytrust Bancorp, Inc.*, 25 F.3d 1124, 1130 (2d Cir. 1994).¹³ Here, plaintiff contends that Flamel engaged in a fraudulent scheme which was doomed to fail (because destined to be exposed within months) -- yet neither sought nor obtained any benefits from the temporary stock price inflation which the scheme supposedly caused. Because Flamel, like the defendants in *Shields*, accrued no benefits "from a short respite from an inevitable day of reckoning," plaintiff's theory "defies economic reason" and must be rejected. *Id.*¹⁴

Further undermining plaintiff's theory is that Flamel acted in a manner contrary to its supposed knowledge of COREG CR's limited sales potential. As shown by the Flamel disclosure plaintiff quotes, Flamel reported on August 1, 2007 that, because of the "strong ongoing potential" of COREG CR, "[w]e continue to manufacture at the maximum rate and expect to do so even after the addition of new manufacturing capacity." (AC ¶ 26.) Plaintiff

¹³ *Accord Kalnit v. Eichler*, 264 F.3d 131, 140-41 (2d Cir. 2001)(affirming dismissal of complaint because it defied economic reason); *In re JP Morgan Chase Sec. Litig.*, 02 Civ. 1282 (SHS), 2007 WL 950132, at *3, 13 (S.D.N.Y. Mar. 29, 2007)(rejecting claim where "plaintiffs did not provide a rational incentive for the alleged fraud"); *Hampshire Equity Partners II, L.P. v. Teradyne, Inc.*, 04 Civ. 2218 (LAP), 2005 WL 736217, at *3 (S.D.N.Y. Mar. 30, 2005)("[a]s a matter of law ... allegations of irrational motive cannot support a fraud claim"); *Fadem*, 352 F. Supp. 2d at 511 (same); *Duane Reade Inc.*, 2003 WL 22801416, at *9 n.22 (fraud claim that is "'belied by logic'" must fail).

¹⁴ *See also In re Geopharma, Inc.*, 399 F. Supp. 2d at 449-50 (rejecting alleged scheme because it "could not possibly have succeeded").

offers no reason why Flamel would invest substantial resources to manufacture at "maximum rate" a product which, under plaintiff's theory, Flamel knew would prove largely unmarketable. Because plaintiff's claim rests on the assumption that Flamel nevertheless pursued such a nonsensical course contrary to its "informed economic self-interest," the claim must fail. *See Fadem*, 352 F. Supp. 2d at 511 (rejecting fraud theory premised on assertion that company purchased more product "than it knew or thought it would need").¹⁵

2. Plaintiff fails to allege facts showing recklessness

Although plaintiff's failure to allege any motive to commit fraud is not dispositive of her claim, "the strength of the circumstantial allegations" of conscious recklessness -- the alternative approach to pleading scienter¹⁶ -- "must be correspondingly greater." *Kalnit*, 264 F.3d at 142. Plaintiff's "circumstantial allegations", however, are entirely threadbare, consisting solely of conclusory assertions which do not raise a strong inference of scienter.

To plead conscious recklessness, plaintiff must "allege facts approaching *a knowledgeable participation in the fraud or a deliberate and conscious disregard of facts.*" *In re Bayou Hedge Fund Litig.*, 534 F. Supp. 2d 405, 415 (S.D.N.Y. 2007)(original emphasis). In particular, plaintiff must have "specifically alleged defendants' knowledge of facts or access to

¹⁵ *See also JP Morgan Chase Sec. Litig.*, 2007 WL 950132, at *3 (rejecting contention that lender knew its borrower was "on the verge of collapse" when lender "continue[d] to extend billions of dollars in credit" to the borrower); *Faulkner v. Verizon Communications, Inc.*, 189 F. Supp. 2d 161, 171 & n.2 (S.D.N.Y. 2002)(rejecting as illogical claim that investor sought to bankrupt third-party and defraud its noteholders by not performing its contract duties where investor expended a "significant amount of capital" in partial performance of the contract).

¹⁶ "Conscious misbehavior," another means of pleading scienter, is not at issue here. Such conduct requires a showing of "deliberate illegal behavior, such as securities trading by insiders privy to undisclosed and material information, or knowing sale of a company's stock at an unwarranted discount." *Goplen*, 453 F. Supp. 2d at 773. Plaintiff does not purport to accuse defendants of engaging in such illegal behavior.

information contradicting their public statements." *Goplen*, 453 F. Supp. 2d at 773.¹⁷ Those specific factual allegations do not appear in the Amended Complaint.

To the contrary, plaintiff's claim of recklessness rests entirely on the following two assertions:

- Flamel "commenced" the CASPER Trial to measure patient's "differential compliance" with taking COREG IR compared with COREG CR; and
- prior to March 23, 2007, the results of the CASPER Trial -- *i.e.*, that patient's compliance rates did not substantially improve with COREG CR -- were "made known" to Flamel.

(AC ¶ 18-19.)

These allegations fail to supply the essential "factual basis for the allegation that the defendants knew or should have known" that their statements were false when made. *Goplen*, 453 F. Supp. 2d at 767-68. For example, plaintiff's claim that Flamel "commenced" the CASPER Trial lacks any factual support for such a conclusion. Worse still, plaintiff's assertion that the results of the CASPER Trial were "made known" to Flamel prior to March 23, 2007 is purely of product of plaintiff's *ipse dixit*.¹⁸

Wholly absent from the Amended Complaint is any factual averment -- *e.g.*, a specifically identified document, public statement or percipient witness's testimony -- linking

¹⁷ *Accord Kalnit*, 264 F.3d at 142; *Caiafa v. Sea Containers Ltd.*, 525 F. Supp. 2d 398, 412 (S.D.N.Y. 2007); *eSpeed, Inc.*, 457 F. Supp. 2d at 292.

¹⁸ Plaintiff attempts to manufacture a veneer of factual detail by alleging that the results of the CASPER Trial must have been known sometime before April 9, 2007, because that supposedly was the date for the submission of abstracts to the *Journal of Cardiac Failure*. (AC ¶ 19.) Even assuming April 9, 2007 was the submission deadline -- an assertion which itself is factually unsupported -- that minor detail affords no basis to infer that Flamel knew the results of the CASPER Trial, or had reviewed the CASPER Trial abstract, anytime before its August 23 2007 publication in the *Journal*. In other words, while the authors of the CASPER Trial abstract presumably knew the Trial results before submitting their draft to the *Journal*, plaintiff alleges no facts to suggest that the authors communicated their findings to Flamel.

knowledge of the results of the CASPER Trial to anyone at Flamel, let alone an individual defendant, **before** the August 23, 2007 publication of the CASPER Trial abstract. These "omissions ... count against inferring scienter." *Tellabs*, 127 S.Ct. at 2511. Indeed, courts have consistently dismissed recklessness claims similar to this one which rely on conclusory assertions to connect a defendant to knowledge contradicting his public statements -- rather than facts raising a strong inference of such knowledge. *See, e.g., Fadem*, 352 F. Supp. 2d at 522-23 (alleged existence of corporate communications network fails to raise a strong inference of recklessness because "[t]here is no evidence of what information was actually passed through these channels -- what the purchasing and engineering employees actually said to each other, let alone what information, if any, was conveyed to" the individual defendants).¹⁹

While plaintiff's conclusory assertions are themselves insufficient to raise a strong inference of scienter -- and thus warrant dismissal of plaintiff's suit -- the few facts that are pled (and those contained in the documents plaintiffs rely upon) provide a further cogent and compelling rationale for rejecting plaintiff's recklessness claim. Specifically, Flamel's business, as plaintiffs allege, focuses on the invention of "polymer-based delivery technologies" to help

¹⁹ *See also San Leandro*, 75 F.3d at 812 (scienter not shown for defendants' mistakenly positive predictions because "plaintiffs allege no facts supporting their assertion that defendants had knowledge of the" sales decline prior to making their statements); *Elan Corp.*, 2008 WL 839744, at *24 (scienter not pled for allegedly false product safety claims because "allegations do not indicate when the relevant safety data were analyzed or when Defendants in fact became aware of the results"); *Sierra Wireless, Inc.*, 482 F. Supp. 2d at 375 (rejecting assertion that defendant recklessly made misleading projection because "plaintiffs supply no facts whatsoever to support their allegations that [defendant] knew about the termination of its existing business with" its customer when projections were made); *Hampshire Equity Partners*, 2005 WL 736217, at *4 (dismissing fraud claim because "[v]ague and conclusory allegations that a defendant allegedly had access to non-public information ... do not suffice" to plead scienter); *In re Cross Media Marketing Corp. Sec. Litig.*, 314 F. Supp. 2d 256, 269 (S.D.N.Y. 2004) (rejecting scienter allegation because the complaint "does not allege that Defendants had received a report showing a material adverse impact on sales" prior to making optimistic projections). *Cf. Goplen*, 453 F. Supp. 2d at 773 ("bare assertions" of defendants' corporate positions "without any further facts or details, do not adequately demonstrate defendants' knowledge of facts or access to information contradicting their public statements").

"pharmaceutical companies develop extended release drugs." (AC ¶ 13.) In contrast, it was GSK -- a major pharmaceutical firm -- that developed and marketed COREG IR and who, using Flamel's technology, developed and marketed COREG CR, the "extended release" version of GSK's original COREG IR drug. (*Id.* ¶¶ 14-15.)

As Flamel reported in its 2006 Form 20-F, the company "market[s] and sell[s] our technologies to third parties, who incorporate our technologies into their products" and relies upon the "pharmaceutical and biotechnology companies to develop, test, obtain regulatory approval for and commercialize products that incorporate our drug delivery technologies." (Flamel 2006 Form 20-F at 3 [Wertheimer Decl. Ex. B].)²⁰

Against that background, it is not surprising that Flamel would not have known of the CASPER Trial results before the abstract's publication. Moreover, all the facts alleged are consistent with Flamel being unaware of those Trial results prior to publication. For example, the CASPER Trial abstract does not name Flamel as either a sponsor or author of the Trial. But, one of the abstract's authors, Paul A. Ordonneau, is identified as affiliated with GSK.²¹ Moreover, a description of the CASPER Trial available on the internet website "clinicaltrials.gov" -- and mentioned by defendant Willard, Flamel's CEO, during a May 7, 2007

²⁰ The Court may consider this document on this motion because plaintiff refers to it in her pleading and it was publicly filed with the SEC. *See Goplen*, 453 F. Supp. 2d at 765.

²¹ *See James E. Udelson, et al., Compliance with Once Daily Controlled Release vs Twice Daily Immediate Release Carvedilol in Patients with Heart Failure: The Casper Trial*, 13 *Journal of Cardiac Failure* S135 (August 2007)(Wertheimer Decl. Ex. C.) The Court may consider this document because plaintiff refers to it in the Amended Complaint. *See Goplen*, 453 F. Supp. 2d at 765.

analyst conference call (AC ¶ 25) -- identifies GSK as a "sponsor" and "collaborator" for the Trial but makes no mention of Flamel.²²

In addition, as plaintiffs allege, defendant Willard told securities analysts on May 7, 2007 that it was "GSK's call as to how that [CASPER Trial] data comes out" and on August 2, 2007, that presentation of the CASPER Trial data was "for GSK to be able to tell people about." (AC ¶¶ 25, 27.) These statements are entirely consistent with the conclusion that Flamel did not know the results of the CASPER Trial until publication of the abstract on August 23, 2007.

Furthermore, as discussed above, through at least August 1, 2007, Flamel reported that, due to the potential of COREG CR, "[w]e continue to manufacture at the maximum rate." (AC ¶ 26.) Flamel's investment of capital, facilities and personnel into manufacturing "at the maximum rate" COREG CR microparticles is wholly inconsistent with any inference that Flamel "consciously" disregarded evidence that, according to plaintiff, undermined the "primary selling point" for COREG CR. (AC ¶ 20.) *See, e.g., Geopharma, Inc.*, 399 F. Supp. 2d at 451-52 & n.147 (an illogical scheme "negates any inference of intent to defraud").

* * * *

In sum, plaintiff alleges no facts to show either that Flamel had a motive to commit fraud or knowledge contradicting its public statements at the time they were made. Rather, plaintiff's claim rests solely on the publication of the CASPER Trial abstract after Flamel made the statements at issue and the conclusory assertion that Flamel "must have known" the Trial's results before the purported class period began on March 23, 2007. That argument is a

²² *See Drug Compliance and Quality of Life in Patients with Heart Failure Dosed with Either Once-Daily or Twice-Daily Coreg*, available at <http://clinicaltrials.gov/ct2/show/record/NCT00272805>. (Wertheimer Decl. Ex. D.) The Court may consider this document because it is publicly available, integral to plaintiff's allegations and cited in documents plaintiff relied upon in her pleading. *See Goplen*, 453 F. Supp. 2d at 765.

bald attempt at pleading fraud by hindsight -- a tactic condemned under both Rule 9(b) and the PSLRA. *See Goplen*, 453 F. Supp. 2d at 770. Accordingly, plaintiff's §10(b) claim must fail.²³

II. PLAINTIFF'S §20(A) CLAIM SHOULD BE DISMISSED

An essential element of a claim under §20(a) is proof of a primary violation of §10(b) by the controlled person. *ATSI*, 493 F.3d at 108. Because plaintiff has failed to allege a §10(b) claim against any of the defendants in this action, her §20(a) claim must also fail. *Id.* *Accord Goplen*, 453 F. Supp. 2d at 775; *Fadem*, 352 F. Supp. 2d at 526.

CONCLUSION

For the reasons set forth above, all claims asserted against Flamel should be dismissed. Moreover, because plaintiff has already amended her pleading once and because plaintiff can allege no facts which would render Flamel's March 23, 2007 press release materially misleading, her suit should be dismissed with prejudice. *See, e.g., Cortec Indus., Inc. v. Sum Holding L.P.*, 949 F.2d 42, 48 (2d Cir. 1991)("where a plaintiff is unable to allege any fact sufficient to support its claim, a complaint should be dismissed with prejudice"); *Duane Reade Inc.*, 2003 WL 22801416, at *10 n.23 (leave to replead not appropriate "given the [complaint's] particular deficiencies and the fact that the complaint is both amended and consolidated").

²³ Needless to say, the defects in plaintiff's scienter pleading as to Flamel apply equally to the individually named defendants. Indeed, plaintiff's only basis for pleading scienter as to those defendants is to cite their corporate positions. (AC ¶ 34.) Not only is such a conclusory allegation inadequate in general, *see Goplen*, 453 F. Supp. 2d at 768, but it is particularly improper in this case where no facts are pled to show that anyone at Flamel had access to the results of the CASPER Trial prior to the August publication.

Dated: May 12, 2008

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby declare that on May 12, 2008, I caused a true and correct copy of the foregoing to be electronically filed and to be served, by United States Mail, first-class postage prepaid on counsel for plaintiff at the following address:

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